The need for international stem cell agreements

To the editor:

The feature by Lori Knowles in the February issue (*Nat. Biotechnol.* **22**, 157–163, 2004) outlined embryonic stem (ES) cell regulations around the world and in the United States. Different political bodies are pursuing a wide variety of ES cell policies, ranging from banning the controversial research to nurturing it. This surfeit of policies is not promoting the development of scientifically progressive, economically effective or socially responsible stem cell research. There are sound scientific, economic and ethical reasons for trying to achieve uniform international and national policies on stem cell research.

First, research on ES cells is not limited to any particular nation or state. A lack of uniform policies can inhibit national and international collaboration in stem cell research, which is vital to the development of this new field. In one recent episode, a German professor faced a possible jail sentence for conducting in another country stem cell research that was forbidden in Germany[1].

Geographically diverse policies can also encourage stem cell scientists and research sponsors to migrate to nations or states with 'ES-cell friendly' laws and policies. Already, countries that allow ES cell research, such as the United Kingdom and Singapore, have shown that they are capable of siphoning scientific resources from countries that shun the research, such as Germany and France. The potential for an ES cell 'brain drain' could affect scientific collaboration and strain international relations.

Second, diverse policies can interfere with international and national commerce related to ES cell research because different political bodies might not honor tangible or intellectual property rights in ES cells. As ES cell research and companies develop products with economic clout and an ES cell industry begins to emerge, controversies concerning commerce in ES cells could affect negotiations over trade agreements and intellectual property treaties. For example, countries that do not allow the derivation of stem cells will have to decide how they will respond to the importation of ES cell lines, and countries that do not grant patents on ES cells will have to decide whether they will undermine another country's ES cell patents.

Third, and most important, variations in stem cell policies can have a detrimental impact on the health, safety and rights of patients and research subjects. There are many ethical issues concerning stem cell research and its potential in therapy that need to be resolved, including informed consent for embryo or gamete donors and stem cell recipients, privacy, the use of ES cells for reproduction, the creation of ES cells for research and quality control of stem cells and their products[2]. Patients (or research subjects) who will receive therapy (or take part in experiments) in countries that do not uphold ethical standards for stem cell therapy (or research) may suffer dire consequences from poorly designed therapy or research. To protect patients, research subjects and others, nations (and states) should adopt uniform scientific and ethical standards for stem cell therapy and research[3].

Nations should work separately and together to develop sound and workable national and international policies on ES cell research and its potential therapeutic use. Although different countries disagree on important bioethical issues related to ES cell research, such as cloning for reproduction and abortion, it should be possible to reach agreement on some common ground, such as the need for an international moratorium on reproductive cloning and the importance of informed consent, safety and privacy in biomedical therapy and research.

For many years, the United Nations (UN, New York) has served as a forum for addressing bioethics issues related to human health and human rights. In 2003, the General Assembly of the UN decided to take no action proposals to ban human cloning until the 2005 session[4]. In its next session, the General Assembly should revisit the topic of human cloning with a firm eye toward the need to develop international standards to regulate ES cell research. Individual countries, such as the United States, should also develop national policies designed to harmonize regional and local laws.

This letter does not represent the views of the NIEHS or the NIH.

1. Vogel, G. *Science* **301**, 577 (2003).
2. The President's Council on Bioethics. *Human Cloning and Human Dignity: an Ethical Inquiry* (President's Council on Bioethics, Washington, DC, 2002). http://www.bioethics.gov/
3. Brivanlou, A. *et al. Science* **300**, 913–915 (2003).
4. http://www.un.org/law/cloning/

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Putting Cartagena into practice

To the editor:

We read with interest the piece by Willy de Greef in the July issue (*Nat. Biotechnol.* **22**, 811–812, 2004) describing the impact of the Cartagena protocol on genetically modified (GM) crops. This protocol initially was drafted with an emphasis on protecting biological diversity against the potential risk of deliberate release of living modified organisms (LMOs) into the environment (with human health and socioeconomic aspects of GM supposedly a secondary issue). Yet most of the concerns of developing countries at the First Meeting of the Parties (MOP1) in Kuala Lumpur on February 23–27, 2004—and at recent regional meetings organized by such agencies as the Asia Pacific Economic Cooperation, Association of South East Asian Nations and the Organization of Islamic Conference Standing Committee on Scientific and Technological Cooperation (OIC-COMSTECH)—focused on trade and agricultural issues surrounding GM crops.